

Attorney Docket No.: DEX-0087
Inventors: Recipon et al.
Serial No.: 09/705,500
Filing Date: November 3, 2000
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REMARKS

Claims 1-5 and 12 are pending in the instant application. Claims 1-5 and 12 have been rejected. Claims 1-5 have been amended. Support for the amendments is provided in the specification at page 4, lines 18-22, and page 7, lines 28-32. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 1 and 12 under 35 U.S.C. § 112, second paragraph

Claims 2 and 12 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests that recitation in claim 2 of "identifying a patient having cancer that is not known to have metastasized" and "determining the Lng108 level in the cells, tissues or bodily fluids from said patient" and "wherein an increase in the Lng108 level in the patient versus the normal human control is associated with cancer which has metastasized" is unclear since the method requires a patient free of metastases in section (a) but the presence of

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metastatic cancer in section (c).

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have deleted the phrase "that is not known to have metastasized" from section (a) of claim 2.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

II. Rejection of Claims 1-5 and 12 under 35 U.S.C. § 112, first paragraph

Claims 1 and 12 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for methods of diagnosing the presence of cancer or metastases in patients by measuring an increase in the level of the Lng108. However, the Examiner suggests that the specification does not reasonably provide enablement for methods of diagnosing the presence of cancer or metastases in patients by measuring any change in the level of the Lng108 which is not an increase.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 by replacing the term "change" with --increase--.

Claims 1-5 and 12 have also been rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed had possession of the claimed invention. In particular, the Examiner suggests that the specification does not set forth any written description of hybridizing polynucleotides.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have been amended the claims to remove this phrase.

Withdrawal of these rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

III. Rejection of Claims 1, 2 and 12 under 35 U.S.C. § 102(e)

Claims 1, 2 and 12 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Olsen et al. (Pub. No. U.S. 2002/0042372). The Examiner suggests that Olsen disclose methods of detecting cancer and metastatic cancer comprising detecting stanniocalcin which aligns with SEQ ID NO:3 of the present invention.

Applicants respectfully traverse this rejection.

While the published U.S. application of Olsen mentions a whole host of potential uses for stanniocalcin, there is absolutely no enabling support or data for the conjecture in the

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application that stanniocalcin is useful in detecting cancer and metastatic cancer nor detection of metastases of lung carcinoma. The cited paragraphs by the Examiner in Olsen [0382, 0400, 0402, 0421, 0423, 0427, 0428] are merely part of a laundry list of disorders or ailments which further includes Immune Disorders [0391], Hyperproliferative Disorders [0399], Cardiovascular Disorders [0404], Anti-Angiogenesis Activity [0420], Apoptosis [0427], Wound Healing and Cell Proliferation [0430], and Infections Diseases [0439]. No enabling support is found in Olsen that stanniocalcin is useful in detecting any of these disorders listed. In fact, the only enabling support provided in Olsen is for stanniocalcin use in protection of neural cells from hypoxic conditions [0504]. Accordingly, since this reference does not contain an enabling disclosure with respect to the instant claimed invention, it cannot anticipate the instant claimed invention. See MPEP § 2131.01.

Withdrawal of this rejection under 35 U.S.C. § 102(e) is therefore respectfully requested.

IV. Rejection of Claims 1-5 and 12 under 35 U.S.C. § 103(a)

Claims 1-5 and 12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Olsen et al. (Pub. No. U.S. 2002/0042372) in view of Sobol et al. (U.S. Patent 5,543,296).

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The Examiner suggests that it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to monitor patients having cancer, and especially lung cancer over time for the presence of Lng108 in cells, tissues and bodily fluids in order to stage the progress of the cancer. The Examiner suggests that one of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Sobol on the necessity of monitoring for the presence of metastases in patients having lung cancer in order to provide such patients who develop metastatic lesions with appropriate systemic therapy.

Applicants respectfully traverse this rejection.

As discussed in Section III, supra, the published U.S. application of Olsen is not enabling with respect to potential uses for stanniocalcin in diagnosing cancer.

Further the secondary reference of Sobol fails to remedy the deficiencies in the primary reference of Olsen since the teachings of Sobol are unrelated to stanniocalcin.

Accordingly, this combination of references fails to provide any reasonable expectation of success with respect to the instant invention as required to render the instant invention obvious.

Further, even if Olsen were enabling, which it is not, the

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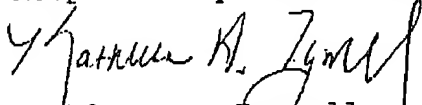
combination of Olsen and Sobel is at best an "obvious to try" rejection. The Court of Appeals for the Federal Circuit has repeatedly held that "obvious to try" rejections are improper.

Withdrawal of this rejection under 35 U.S.C. § 103(a) is therefore respectfully requested.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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